EXHIBIT U

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ALLERGAN USA, INC., and ALLERGAN INDUSTRIE, SAS,

Plaintiffs,

v.

MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

Defendants.

Case No. 8:13-cv-01436 AG (JPRx)

DEFENDANTS' FINAL INVALIDITY CONTENTIONS

Medicis Aesthetics, Inc., Medicis Pharmaceutical Corp., Valeant Pharmaceuticals North America LLC, Valaent Pharmaceuticals International, Valeant Pharmaceuticals International, Inc., and Galderma Laboratories, L.P. (collectively, "Defendants") by their undersigned attorneys, submit the following Final Invalidity Contentions ("Invalidity Contentions") with respect to the asserted claims of U.S. Patent Nos. 8,450,475 ("the '475 patent") and 8,357,795 ("the '795 patent") as identified in Plaintiffs Allergan Industrie, SAS and Allergan USA, Inc.'s (collectively, "Allergan") March 7, 2014 First Supplemental Disclosure of Asserted Claims and Infringement Contentions Pursuant to S.P.R. 2.1 ("Infringement Contentions") and the February 9, 2015 letter from Elizabeth M. Flanagan identifying the claims Allergan would be asserting.

Allergan has identified and asserted the following claims: 1, 2, 4-6, 8-9, 18, and 31-37 of the '475 patent and claims 1, 3, 8, 11, and 41 of the '795 patent. These Invalidity Contentions are based in whole or in part on Defendants' present understanding of Allergan's positions as set forth in its Infringement Contentions, including any underlying interpretations of the claims by Allergan.

Defendants' investigations are ongoing, as is fact discovery. Accordingly, Defendants reserve the right to expand, add, change or otherwise amend their Invalidity Contentions consistent with the Federal Rules of Civil Procedure and the Court's rules, based on their continued investigation, fact discovery, expert discovery, and the Court's claim construction. Defendants also reserve the right to amend their Invalidity Contentions based on any supplementation by Allergan of its Infringement Contentions, or of its document production. Defendants also reserve the right to amend their Invalidity Contentions based on any positions taken by Allergan as to the date of the alleged invention of the asserted claims.

DEFENDANTS' FIRST SUPPLEMENTAL INVALIDITY CONTENTIONS

I. Identification of Prior Art

Pursuant to the Court's Standing Patent Rules and in response to Allergan's Infringement Contentions, Defendants' identify the prior art in the following tables as either anticipating the asserted claims or rendering them obvious, individually or in combination with each other and other prior art. To establish the scope and content of the prior art, a motivation to combine or modify the prior art, or the knowledge and level of skill of those of ordinary skill in the art, Defendants may also rely on (1) non-prior-art patents, patent applications or publications, or other evidence (for example, the prosecution history files of U.S. and foreign patent applications) that may not qualify as prior art under 35 U.S.C. § 102, and (2) statements and admissions made by Allergan and its employees or agents in the patents-in-suit, during prosecution of the patents-in-suit or related patent applications, or in other documents.

The prior art references identified below are presumed to be enabled for all that they disclose. Defendants reserve the right to identify additional prior art evidencing enablement of these references should Allergan challenge the presumption of enablement. Moreover, Defendants reserve their right to assert that the claims of the '475 and '795 patents are indefinite under 35 U.S.C. § 112 and are invalid on other statutory bases after the Court issues a ruling on claim construction.

A. Prior Art Patents and Patent Applications

Patent Number	Country of Origin	Date of Issue or Publication	Abbreviation
WO 96/33751	Int. / FR	Oct. 31, 1996	*Debacker*[1]

[1] All citations to verified English translation provided herewith

Patent Number	Country of Origin	Date of Issue or Publication	Abbreviation
5,731,298	US / German	Mar. 24, 1998 (national phase of WO93/12801 (German), filed Dec. 24, 1992)	*Reinmuller I*
WO 2005/067944	Int. / German	July 28, 2005	*Reinmuller II*[2]
2005/0136122	U.S.	June 23, 2005	*Sadozai*
2008/0226724	U.S.	Sep. 18, 2008, earliest priority date Jan. 19, 2007	*Ji*
2006/0040894	U.S.	Feb. 23, 2006	*Hunter*
WO 2005/112888 A2	Int.	Dec. 1, 2005	*Wang*
2006/0194758	U.S.	Aug. 31, 2006	*Lebreton*
5,079,236	U.S.	Jan. 7, 1992	*Drizen*
6,521,223	U.S.	Feb. 18, 2003	*Calias*

[2] All citations to English equivalent, U.S. Patent No. 7,902,171

B. Prior Art Publications

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Effectiveness of next generation hyaluronic acid dermal fillers in the treatment of severe nasolabial folds"	Feb. 2007	Lupo *et al.*	Abstract of a poster (P2909) presented at the 65th Annual Meeting of the American Academy of Dermatology, Feb. 2-6, 2007, in J. Am Acad Dermatol., 56(2) Supp 3, Feb. 2007, p. AB199	*Lupo*
"Volumetry: new opportunities for rejuvenating and modeling of your facial features"	Sep. / Oct. 2006	Ambroziak, Marcin	Ekspert, a magazine for customers clinic in dermatology and aesthetic medicine, plastic surgery, wellness and beauty spa (in Polish), September/October 2006 [with verified English translation][3]	*Expert Anti-Aging*
"Juvéderm: A Hyaluronic Acid Dermal Filler"	Nov. 2007	Monheit, Gary D. & Prather, Chad L.	*J Drugs Dermatol.* 6(11):1091-5, Nov. 2007	*Monheit*
"Preclinical evaluation of a novel hyaluronic acid 28 mg/ml, lidocaine 0.3% stable combination product"	Feb. 2007	Toth *et al.*	Abstract of a poster (P1039) presented at the 65th Annual Meeting of the American Academy of Dermatology, Feb. 2-6, 2007, Washington, DC, in *J. Am Acad Dermatol.*, 56(2) Supp 3, Feb. 2007, pAB94	*Toth*

[3] All citations herein to *Expert Anti-Aging* are made with reference to the English translation thereof

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Influence of various compounds on the degradation of hyaluronic acid by a myeloperoxidase system"	1994	Lindvall, Sven & Rydell, Gunilla	Chemico-Biological Interactions 90: 1-12 (1994)	*Lindvall*
"Injecting Puragen Plus Into the Nasolabial Folds: Preliminary Observations of FDA Trial"	Nov. 1, 2006	Kinney, Brian M.	Aesthetic Surgery Journal, 26: 741-748 (2006)	*Kinney*
Summary of Safety and Effectiveness of Cosmetic Tissue Augmentation product (CTA) [Elevess]	Issued Dec. 20, 2006, Updated Jan. 10, 2007	FDA	Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p050033, accessed Jan 2, 2014	*Elevess Summary*

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Effectiveness and durability of a hyaluronic acid 28 mg/ml, lidocaine 0.3% stable combination product as demonstrated in a multicenter, randomized trial"	Feb. 2007	Hanke *et al.*	Abstract of a poster (P1040) presented at the 65th Annual Meeting of the American Academy of Dermatology, Feb. 2-6, 2007, Washington, DC, in *J. Am Acad Dermatol.*, 56(2) Supp 3, Feb. 2007, pAB94	*Hanke*
"The many ways to cleave hyaluronan"	July 2007	Stern *et al.*	Biotechnology Advances 25 (2007) 537–557	*Stern*
"Heat-Induced Generation of Reactive Oxygen Species during Reduction of Dissolved Air Oxygen"	August 2001	Bruskov *et al.*	Doklady Akademii Nauk, 381 (2): 262-264, 2001	*Bruskov*
"Degradative Action of Reactive Oxygen Species on Hyaluronan"	Feb. 16, 2006	Šoltés *et al.*	Biomacromolecules 7:*659-668*, 2006	*Soltes*

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Stability of Lidocaine in Aqueous Solution: Effect of Temperature, pH, Buffer and Metal Ions on Amide Hydrolysis"	1987	Powell, Michael F.	Pharmaceutical Research, 4 (1): 42-45, 1987	*Powell*
"Thermal Stability of sodium hyaluronate in aqueous solution"	October 1994	Lowry, Karen M. & Beavers, Ellington M.	*Journal of Biomedical Materials Research*, 28:1239-1244, published 1994	*Lowry*
"Use of hyaluronic acid filleres for the treatment of the aging face"	Sep. 2007	Gold, Michael H.	*Clinical Interventions in Aging*, 2(3): 369-376 (2007)	*Gold*

C. Prior Art On Sale in the United States

Defendants identify the dermal fillers Restylane and Perlane, first approved by the FDA for sale by Q-Med AB in December 2003; Elevess, first approved by the FDA for sale by Anika Therapeutics in December 2006; Juvederm 24HV and Juvederm 30HV, first approved by the FDA for sale by Allergan in June of 2006; and Puragen Plus, which was known and used in the US at least by 2006.

D. Additional Publications

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Hyaluronic Acid Fillers: A Comprehensive Review"	May 2009	Beasley *et al.*	*Facial Plastic Surgery*, 25(2):86-94 (2009)	*Beasley*
"Comparative Physical Properties of Hyaluronic Acid Dermal Fillers"	Feb. 2009	Kablik *et al.*	*Dermatologic Surgery*, 35 Suppl 1:302-12 (2009)	*Kablik*
"A prospective, split-face, randomized, comparative study of safety and 12-month longevity of three formulations of hyaluronic acid dermal filler for treatment of nasolabial folds"	July 2012	Prager *et al.*	*Dermatologic Surgery*, 38(7 Pt 2):1143-50 (2012)	*Prager*
"Volumizing effects of a smooth, highly cohesive, viscous 20-mg/mL hyaluronic acid volumizing filler: prospective European study"	2009	Hoffman, Klaud	*BMC Dermatology* , **9**:9 (2009)	*Hoffman*

Title	Date of Publication	Author	Publisher/Source	Abbreviation
"Mentor Corporation Announces FDA Approval of Prevelle Silk"	March 21,2008	Bloomberg News	Bloomberg News, available at http://www.bloomberg.com/apps/news?pid=newsarchive&sid=arVm09DtlA5c, accessed Jan 2, 2014	*Prevelle Announcement*
Excerpt of FDA Advisory Committee Briefing Document, Juvederm Voluma™ XC	May 2, 2013	Allergan	*FDA*	*Juvederm FDA Briefing*

II. The Prior Art Anticipates or Renders Obvious the Asserted Claims of the '475 and '795 Patents

Pursuant to the Standing Patent Rules and in response to Allergan's Infringement Contentions, Defendants set forth their contentions as to whether each of the identified items of prior art anticipate each asserted claim of the '475 and '795 patents and/or render the claims obvious. Citations to the prior art references are exemplary; other support for Defendants' Invalidity Contentions may be found elsewhere in the cited references. These charts and citations, at least in part, are based upon the positions taken by Allergan in its Infringement Contentions, without Defendants necessarily adopting the positions reflected therein. The identification of structure or processes in the prior art are not intended to necessarily reflect Defendants' claim interpretations, either directly or by implication.

The citations provided below and in the attached claim charts are representative of the teachings of the listed references. Defendants reserve the right to modify these statements and charts by adding additional prior art references to the extent such modification is appropriate in light of any

additional information gained through ongoing investigations or through discovery or in light of amendments to Allergan's infringement contentions or other arguments made or positions taken by Allergan.

A. The Asserted Claims of the '475 and '795 Patents are Invalid under 35 U.S.C. § 103

Defendants set forth below and in their claim charts in the attached Exhibits A and B where each claim limitation of the asserted claims of the '475 patent and the '795 patent may be found in the disclosed prior art references identified above, rendering the asserted claims obvious. The claim charts and teachings of each of the listed references may be used in combination with each other and with other references. Generally, the motivation to combine or modify the prior art references may be found in the prior art references themselves, either expressly or impliedly, as filtered through the knowledge of one of ordinary skill in the art; in common sense or common knowledge; in the knowledge of those of ordinary skill in the art, taking into account the inferences and creative steps that such a person would employ; in the prior art as a whole; and/or from the nature of the problem to be solved. Moreover, all prior art identified above in I.A-C is in the same field of endeavor: dermal fillers. Therefore, such a modification would be a routine arrangement of known elements in a common field of endeavor, with each element performing the same function it had been known to perform, yielding no more than what one would expect from such an arrangement.

As disclosed in the '475 patent, HA based soft tissue fillers were known and under rapid development since the FDA approval of the first HA-based soft tissue filler in December, 2003 (*'475 patent*, 1:63-65). HA crosslinked with each of four crosslinkers, i.e., 1,4-butanediol diglycidyl ether (BDDE), divinylsulfone (DVS), 1,2,7,8-diepoxyoctane (DEO) and p-phenylene bis(ethyl)carbodiimide (BCDI), had been used in approved soft tissue fillers for increased stability and durability. Uncrosslinked HA had been commonly used together with the crosslinked HA to

reduce the extrusion force and ease the injection. More specifically, wrinkle fillers containing HA-BDDE and uncrosslinked HA had been disclosed, such as Juvederm® Ultra (J24HV) and Juvederm® Ultra Plus (J30HV) (*Lupo)*, which contains HA-BDDE and at least 10% uncrosslinked or free HA (see *Beasley*, Table 1); the two phase filler composition described in Example 2 of *Debacker*, which contains HA-BDDE and 33% uncrosslinked HA; and the composition disclosed in *Reinmuller II.* The crosslinked HA can have a mixture of high- and low-molecular weight HA (see *Lebreton).*

Pain is a barrier to cosmetic treatment. Lidocaine had been included in various filler products to reduce the pain. Dermal fillers, such as Puragen® Plus, Elevess® and Prevelle® Silk, containing lidocaine and HA crosslinked with each of three different crosslinkers, DEO, BCDI and DVS, respectively, had been approved and reported prior to August 2008 (*Kinney*, *Elevess™ Summary*, and *Prevelle® Announcement*). Puragen® Plus and Prevelle® Silk also contain uncrosslinked HA, i.e., 6% and 2%, respectively. Preclinical and clinical studies had demonstrated that dermal fillers containing crosslinked HA and lidocaine were stable, effective and durable (see, e.g., *Toth* and *Hanke*). Indeed, a heat sterilized injectable gel containing a crosslinked HA and lidocaine was described in a PCT application filed as early as Dec 24, 1992 (*Reinmuller I*, Example 1).

As a medical device to be injected into a human body, an HA filler must be sterile. Heat sterilization or autoclaving had been used to sterilize almost any type of HA preparations before 2008, crosslinked and/or uncrosslinked HA, with or without lidocaine (*Drizen*, 7:19-25; *Lebreton*, Examples 3-4; and *Debacker*, page 14, lines 22-24 and Example 2; *Sadozai*, Example 12; and *Reinmuller I*, Example 1). Although crosslinked or uncrosslinked HA may be subject to degradation during autoclaving, the sterilized HA fillers can remain stable for months or even years (*Drizen*, 7:44-46; *Lowry*, p1244).

The prior art reported that lidocaine stabilized HA. For example, *Sadozai*, a prior art reference disclosed in the priority documents (e.g., U.S. Prov. App. No. 61/085,956 filed Aug. 4,

2008, 2:25 to 3:9), but omitted in the '475 patent, specifically teaches that "crosslinked HA with lidocaine can have good biostability, and can in some cases have a synergistic effect, increasing G' (the storage modulus)" (*Sadozai*, Example 21). This is consistent with the prior art teaching that adding free radical scavenger to an HA hydrogel decreases viscosity loss due to heat and/or storage (*Ji*, paras. [0061]-[0064]); lidocaine is a potent hydroxyl radical scavenger and singlet oxygen quencher (*Das*); and lidocaine was shown to inhibit HA degradation by the mechanism of hydroxyl radical (*Lindvall*). Moreover, in light of the court's claim construction ruling, stability requires the maintenance of only one property, including sterility, and is tied to no particular time frame.

More specifically, dermal fillers containing lidocaine and a mixture of HA-BDDE and at least 10% uncrosslinked HA (such as some Juvederm® products) had been disclosed in multiple prior art references before August 4, 2008 (see, e.g., *Reinmuller II* and *Hunter*).

Accordingly, as of August 4, 2008, the subject matter claimed in the asserted claims of the '475 and '795 patents was well known and obvious to a person of ordinary skill in the art..

B. The Asserted Claims of the '475 and '795 Patents are Invalid under 35 U.S.C. § 102

1. All of the asserted claims are anticipated by *Hunter*, *Sadozai*, and *Reinmuller II*

Hunter discusses the many uses of hyaluronic acid, especially when combined with other molecules. Restylane itself is mentioned by name multiple times. *See, e.g.*, paragraph 0178. *Hunter* further notes that the composition (one example of which is disclosed to be Restylane) "may further comprise an anesthetic such as lidocaine[.]" Paragraph 0183. As Restylane-L® is merely the earlier Restylane compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe all of the asserted claims of the '475 patent, then the asserted claims are anticipated by *Hunter*.

Similarly, *Sadozai* describes a method for composing, stabilizing, and administering a stabilized hyaluronic acid composition. Within the specification, *Sadozai* specifically references

both Restylane and Perlane as examples when discussing this HA composition. Paragraph 0105. *Sadozai* continues to note the benefits of incorporating lidocaine into such an HA composition, including the benefit of increased stability. Paragraph 0107. Again, as Restylane-L® is merely the earlier Restylane compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe all of the asserted claims of the '475 patent, then the asserted claims are anticipated by *Sadozai*.

Reinmuller II describes hyaluronic acid compositions to be used in the treatment of inflammatory diseases, in particular skin diseases or mucous membrane diseases. The specification of *Reinmuller II* notes that "[h]yaluronic acid is commerically obtainable in the crosslinked state (e.g. … Restylane from Q-Med). Col. 2, lns. 21-26. *Reinumller II* discloses that "[i]n addition to the active compound hyaluronic acid, the pharmaceutical compositions according to the invention can optionally also contain still further pharmaceutical active compounds which are compatible with hyaluronic acid in the course of application, e.g. … local anesthetics (of the lidocaine or novocaine type). Col. 2, lns. 54-63. Again, as Restylane-L® is merely the earlier Restylane compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe all of the asserted claims of the '475 patent, then the asserted claims are anticipated by *Reinmuller II*.

2. Some asserted claims of the '795 Patent are anticipated by *Wang* and the pre-mixing of lidocaine performed by practitioners

Wang teaches processes for preparing injectable HA gels that contain HA-BDDE. Examples 1-7 of *Wang* are crosslinked HA gels that can include BDDE as a crosslinker. These gels described by *Wang* are described as usable for "soft tissue augmentation". *Wang*, 2:1-4. *Wang* additionally instructs the inclusion of anesthetics, such as lidocaine. *Id.*, 7:3-7. The gel was sterilized via autoclaving. *Id.* at 7:23-24. As a result of these disclosures, *Wang* anticipates Claims 1, 3, and 8 of the '795 Patent.

Additionally, practitioners would pre-mix Restylane and Juvederm products with lidocaine before injecting into their patients. These combinations produced a clinically viable filler that remained sterile. This pre-mixing anticipates Claims 1, 3, and 8 of the '795 Patent.

3. Anticipation and Obviousness Charts

Charts providing more detail on the above-listed anticipation arguments as well as the obviousness arguments for both the '475 and '795 Patents can be found attached.

Dated: February 17, 2015

PATTERSON BELKNAP WEBB & TYLER LLP

By: /s/ William F. Cavanaugh, Jr.
William F. Cavanaugh, Jr.

Attorneys for Defendants
MEDICIS AESTHETICS, INC., MEDICIS PHARMACEUTICAL CORP., VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS INTERNATIONAL,
and VALEANT PHARMACEUTICALS INTERNATIONAL, INC.

PROOF OF SERVICE

I am employed in the County of New York, my business address is Patterson Belknap Webb & Tyler LLP, 1133 Avenue of the Americas, New York, New York 10036. I am over the age of 18 and not a party to the foregoing action.

On February 18, 2015, I caused a copy of the following document(s):

DEFENDANTS' FINAL INVALIDITY CONTENTIONS

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I declare under penalty of perjury that the above is true and correct. Executed on February 18, 2015, at New York, NY.

/s/ William F. Schmedlin
William F. Schmedlin

***Pre-mixing by Practitioners*:**

The '475 patent	Prior Art Evidencing Obviousness of '475 Patent Claims
Claim 1	
A stable, sterile soft tissue filler comprising: paragraph	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.
a hyaluronic acid (HA) component comprising HA crosslinked with 1,4-butanediol diglycidyl ether (BDDE), and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.
uncrosslinked HA, wherein the HA component comprises greater than about 10% uncrosslinked HA by volume; and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.
lidocaine combined with said crosslinked HA component.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 1 of the '475 patent, then this element was already known in the art.
Claim 2	
The soft tissue filler of claim 1 wherein the HA component comprises at least about 15% uncrosslinked HA by volume.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 2 of the '475 patent, then this element was already known in the art.
Claim 4	
The soft tissue filler of claim 1 wherein the HA component comprises a first portion of crosslinked HA and a second portion of uncrosslinked HA.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 4 of the '475 patent, then this element was already known in the art.

Claim 5	
The soft tissue filler of claim 4 wherein the first portion has degree of crosslinking of less than about 6%.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 5 of the '475 patent, then this element was already known in the art.
Claim 6	
The soft tissue filler of claim 4 wherein the HA component has a degree of crosslinking of less than about 5%.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 6 of the '475 patent, then this element was already known in the art.
Claim 8	
The soft tissue filler of claim 1 wherein the lidocaine is at a concentration of between about 0.1% and about 5% by weight of said soft tissue filler.	To the extent the lidocaine added by practitioners did not fall within the claimed range, multiple resources pointed to lidocaine concentrations in the ranges covered by the claim element. *See, e.g., Toth* ("a stable formulation of cross linked HA (28 mg/ml) and lidocaine (0.3%) was developed"; *Sadozai*, paragraph [0068] ("…the composition is stabilized, by the inclusion of a local anesthetic, e.g., lidocaine"; *Sadozai*, example 21 ("Crosslinked HA of Example 5 was processed as in Example 12 using three separate buffers 1 (no lidocaine), 2 (0.2% lidocaine), and 3 (0.3% lidocaine)."); *Reinmuller 1*, 7:1-15.
Claim 9	
The soft tissue filler of claim 1 wherein the HA component comprises particles of crosslinked HA in a relatively fluidic medium of uncrosslinked HA.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 9 of the '475 patent, then this element was already known in the art.
Claim 18	
A stable, sterile soft tissue filler comprising:	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 18 of the '475 patent, then this element was already known in the art.
a hyaluronic acid (HA) component crosslinked with 1,4-butanediol diglycidyl ether (BDDE),	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 18 of the '475 patent, then this element was already known in the art.

said HA component having a degree of crosslinking of less than about 5% and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 18 of the '475 patent, then this element was already known in the art.
uncrosslinked HA in an amount of at least about 10% by volume of the HA component; and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 18 of the '475 patent, then this element was already known in the art.
lidocaine having a concentration of about 0.3% by weight of said soft tissue filler;	To the extent the lidocaine used by practitioners did not fall within this claimed range, multiple resources pointed to lidocaine concentrations in the ranges covered by the claim element. *See*, *e.g.*, *Toth* ("a stable formulation of cross linked HA (28 mg/ml) and lidocaine (0.3%) was developed"; *Sadozai*, paragraph [0068] ("…the composition is stabilized, by the inclusion of a local anesthetic, e.g., lidocaine"; *Sadozai*, example 21 ("Crosslinked HA of Example 5 was processed as in Example 12 using three separate buffers 1 (no lidocaine), 2 (0.2% lidocaine), and 3 (0.3% lidocaine)."); *Reinmuller 1*, 7:1-15.
wherein the soft tissue filler has been heat sterilized.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 18 of the '475 patent, then this element was already known in the art.
Claim 31	
A heat-sterilized, stable dermal filler comprising:	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 31 of the '475 patent, then this element was already known in the art.
a hyaluronic acid (HA) comprising both crosslinked HA and uncrosslinked HA,	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 31 of the '475 patent, then this element was already known in the art.
the crosslinked HA being crosslinked with 1,4-butanediol diglycidyl ether (BDDE) and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 31 of the '475 patent, then this element was already known in the art.
having a degree of crosslinking of less than about 5%; and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 31 of the '475 patent, then this element was already known in the art.

lidocaine at a concentration of about 0.3% by weight of said dermal filler;	To the extent the lidocaine added by practitioners did not fall within this claimed range, multiple resources pointed to lidocaine concentrations in the ranges covered by the claim element. *See, e.g.*, *Toth* ("a stable formulation of cross linked HA (28 mg/ml) and lidocaine (0.3%) was developed"; *Sadozai*, paragraph [0068] ("…the composition is stabilized, by the inclusion of a local anesthetic, e.g., lidocaine"; *Sadozai*, example 21 ("Crosslinked HA of Example 5 was processed as in Example 12 using three separate buffers 1 (no lidocaine), 2 (0.2% lidocaine), and 3 (0.3% lidocaine)."); *Reinmuller 1*, 7:1-15.
the dermal filler having a pH of about 7.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 31 of the '475 patent, then this element was already known in the art.
Claim 32	
The dermal filler of claim 31 having a HA concentration of between about 20 mg/mL to about 30 mg/mL.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 32 of the '475 patent, then this element was already known in the art.

Claim 33	
The dermal filler of claim 31 wherein the HA comprises at least about 10% to about 20% of the uncrosslinked HA by volume.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 33 of the '475 patent, then this element was already known in the art.
Claim 34	
A stable, sterile soft tissue filler comprising:	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 34 of the '475 patent, then this element was already known in the art.
a hyaluronic acid (HA) component comprising HA crosslinked with 1 ,4- butanediol diglycidyl ether (BDDE), and uncrosslinked HA; and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 34 of the '475 patent, then this element was already known in the art.
lidocaine at a concentration of about 0.3% by weight of the soft tissue filler combined with said crosslinked HA component;	To the extent the lidocaine added by practitioners was not within this claimed range, multiple resources pointed to lidocaine concentrations in the ranges covered by the claim element. *See, e.g., Toth* ("a stable formulation of cross linked HA (28 mg/ml) and lidocaine (0.3%) was developed"; *Sadozai*, paragraph [0068] ("…the composition is stabilized, by the inclusion of a local anesthetic, e.g., lidocaine"; *Sadozai*, example 21 ("Crosslinked HA of Example 5 was processed as in Example 12 using three separate buffers 1 (no lidocaine), 2 (0.2% lidocaine), and 3 (0.3% lidocaine)."); *Reinmuller 1*, 7:1-15.
wherein the soft tissue filler is stable after heat sterilization at between about 120 degrees C. and about 130 degrees C.; and	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 34 of the '475 patent, then this element was already known in the art.
wherein the soft tissue filler has a pH of about 7.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. This product would inherently be controlled to about 7 to allow for injection into the human body. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 34 of the '475 patent, then this element was already known in the art.
Claim 35	

The soft tissue filler of claim 34 having a HA concentration of between about 20 mg/mL to about 30 mg/mL.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 35 of the '475 patent, then this element was already known in the art.
Claim 36	
The soft tissue filler of claim 34 wherein the HA comprises at least about 10% to about 20% of the uncrosslinked HA by volume.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 36 of the '475 patent, then this element was already known in the art.
Claim 37	
The soft tissue filler of claim 34 wherein the crosslinked HA has a degree of crosslinking of less than about 5%.	Practitioners would premix HA-BDDE dermal fillers such as Restylane® and the early Juvederm products with lidocaine. The practitioner would then inject the dermal filler into a patient. As Restylane-L® is merely the earlier Restylane® compound with the addition of lidocaine, and as Restylane-L® is alleged by Allergan to infringe claim 37 of the '475 patent, then this element was already known in the art.